PATENT

Attorney Docket No.: SALK3130-1J

(088802-9705)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Downes et al.

Application No.:

10/535,041

Filing Date:

May 13, 2005

For: NON-STEROIDAL FARNESOID X

RECEPTOR MODULATORS

Group Art Unit: 1645

RECEIVED CENTRAL FAX CENTER

Examiner: Unknown

DEC 2 8 2005

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the United States Patent and Trademark Office, Washington, D.C., on

the date below.

Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450 1 3 FEB 2006

Legal Staff International Divis**ion** 

#### **DECLARATION OF FACTS IN SUPPORT OF PETITION UNDER 37 C.F.R. § 1.47**

- I, Sheila R. Kirschenbaum, declare that:
- I, Sheila R. Kirschenbaum, am Patent Counsel to Applicant, the Salk Institute for 1. Biological Studies, located in La Jolla, CA.
- Inventors Michael Downes and Ronald Evans were employed by the Salk Institute for 2., Biological Studies at the time of conception of the invention.
- Inventors Robert Hughes, K.C. Nicolaou and Anthony J. Roecker were employed by The 3. Scripps Research Institute located in La Jolla, CA at the time of conception of the invention.
- Thomas Fitting, Esq., Ph.D. is Chief Patent Counsel to The Scripps Research Institute, 4. and is the legal representative of Messrs. Hughes, Nicolaou and Roecker with respect to patent matters.

FOLLY 8587926773

In re Application of: Downes et al. Application No.: 10/535,041

Filing Date: May 13, 2005

Page 2

PATENT Attorney Docket No.: SALK3130-1J (088802-9705)

- A Declaration by Inventor for signature by Messrs. Hughes, Nicolaou and Roecker in 5. United States Application No. 10/535,041 along with copies of the application were sent to Dr. Fitting, Esq. via Federal Express courier service on August 12, 2005. Dr. Fitting, as legal representative of Messrs. Hughes, Nicolaou and Roecker, was informed in an accompanying letter (Exhibit A) of the requirement that each inventor named on United States Application No. 10/535,041, including Messrs. Hughes, Nicolaou and Roecker, execute a Declaration by Inventor.
- No Declaration by Inventor in United States Application No. 10/535,041, signed by 6. Messrs. Hughes Nicolaou or Roecker was received in response to the request described in point 5.
- Dr. Fitting, Esq., in a telephone conversation on October 26, 2005, acknowledged receipt 7. of my letter dated August 12, 2005 requesting signatures on a Declaration by Inventors. Dr. Fitting, Esq. informed me that the matter including the Declaration by Inventor was being "reviewed by the tech transfer office".
- Ms. Jennifer Dyer, Director of Technology Development at The Scripps Research 8. Institute, in a telephone conversation on December 5, 2005 informed me that Scripps inventors would not be signing the Declaration by Inventor.
- I informed Dr. Fitting. Esq. of my telephone conversation with Ms. Dyer by letter 9. (Exhibit B), sent via facsimile and e-mail on December 7, 2005,.
- 10. Dr. Fitting, Esq., in a telephone conversation on December 14, 2005, acknowledged receipt of my letter of December 7, 2005. Dr. Fitting, Esq. again stated that none of the Scripps inventors would be signing the Declaration by Inventor.

In re Application of: Downes et al. Application No.:

10/535,041

Filing Date: May 13, 2005

Page 3

PATENT

Attorney Docket No.: SALK3130-1J

(088802-9705)

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date 27 December 2005

Patent Counsel. The Salk Institute Atty. Dkt. No. SALK 3130-1J (088802-9705)

#### **DECLARATION AND POWER OF ATTORNEY**

As a below named inventor, I HEREBY DECLARE:

THAT my residence, post office address, and citizenship are as stated below next to my name;

THAT I believe I am the original, first, and sole inventor (if only one inventor is named below) or an original, first, and joint inventor (if plural inventors are named below or in an attached Declaration) of the subject matter which is claimed and for which a patent is sought on the invention entitled

## NON-STEROIDAL FARNESOID X RECEPTOR MODULATORS Attorney Docket No. SALK 3130-1J (088802-9705)

the specification of which (check one)

is attached hereto.

<u>X</u> was filed on <u>05/13/2005</u> as United States Application Number <u>10/535,041</u> based on PCT International Application Number <u>PCT/US2003/036123</u> filed on <u>11/14/2003</u> and was amended on <u>5/13/2005</u> (if applicable).

THAT I do not know and do not believe that the same invention was ever known or used by others in the United States of America, or was patented or described in any printed publication in any country, before I (we) invented it;

THAT I do not know and do not believe that the same invention was patented or described in any printed publication in any country, or in public use or on sale in the United States of America, for more than one year prior to the filing date of this United States application;

THAT I do not know and do not believe that the same invention was first patented or made the subject of an inventor's certificate that issued in any country foreign to the United States of America before the filing date of this United States application if the foreign application was filed by me (us), or by my (our) legal representatives or assigns, more than twelve months (six months for design patents) prior to the filing date of this United States application;

THAT I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment specifically referred to above;

THAT I believe that the above-identified specification contains a written description of the invention, and of the manner and process of making and using it, in such full, clear,

023.272782.1

Page 1 of 4

concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention, and sets forth the best mode contemplated by me of carrying out the invention; and

THAT I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I HEREBY CLAIM foreign priority benefits under Title 35, United States Code §119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate or of any PCT international application having a filing date before that of the application on which priority is claimed.

		Priority	Certified
Country	Foreign Filing Date	Claimed?	Сору
			Attached?
	Country	Country Foreign Filing Date	Country Foreign Filing Date Priority Claimed?

I HEREBY CLAIM the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below.

U.S. Provisional Application Number	Filing Date
60/426664	11/15/2002

I HEREBY CLAIM the benefit under Title 35, United States Code, §120 of any United States application(s), or § 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent	PCT Parent	Parent	Parent
Application Number	Application Number	Filing Date	Patent Number
10/658115		9/8/2003	

Page 2 of 4

023,272782.1

I HEREBY APPOINT the registered attorneys and agents at Customer Number

#### 30542

to have full power to prosecute this application and any continuations, divisions, reissues, and reexaminations thereof, to receive the patent, and to transact all business in the United States Patent and Trademark Office connected therewith.

I request that all correspondence be directed to:

Stephen E. Reiter FOLEY & LARDNER LLP Customer Number: 30542

Telephone: (858) 847-6711 Facsimile: (858) 792-6773

I UNDERSTAND AND AGREE THAT the foregoing attorneys and agents appointed by me to prosecute this application do not personally represent me or my legal interests, but instead represent the interests of the legal owner(s) of the invention described in this application.

I FURTHER DECLARE THAT all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Name of first inventor	Michael R. Downes	
Residence	San Diego, California	_
Citizenship	Australia	-
Post Office Address	San Diego, California 92122 9217	-ANE me
Inventor's signature	0	-
Date	8/17/05	-

023.272782.1

Page 3 of 4

		(088602-970
	Name of second inventor	Ronald M. Evans
•	Residence	La Jolla, California
•	Citizenship	United States of America
	Post Office Address	1471 Cottontail Lane
	Inventado -!	La Jolla, California 92037
	Inventor's signature	
	Date	
3 - 00	Name of third inventor	Robert Hughes
	Residence	Crove Cours 36
	Citizenship	
	Post Office Address	Great Britain
	- on omoc Address	800 N. Lindberg, Q403 Creve Couer, Missouri 63167
	Inventor's signature	olove coder, Missouri 63167
	Date	
	_	
4	Name of fifth inventor	Kyriacos C Nicolaou
	Residence	La Jolla, California
	Citizenship	United States of America
	Post Office Address	9625 Blackgold Road
	Instantant	La Jolla, California 92037
	Inventor's signature	
	Date	
- co ,	Name of fourth inventor	Anthony J Roecker
	Residence	San Diego, California
	Citizenship —	United States of America
	Post Office Address	3337 Clairemont Drive, #4
		San Diego, California 92117
	Inventor's signature	
	Date	
	-	

5

عوج أسخو

Atty. Dkt. No. SALK 3130-1J (088802-9705)

## DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I HEREBY DECLARE:

THAT my residence, post office address, and citizenship are as stated below next to my name;

THAT I believe I am the original, first, and sole inventor (if only one inventor is named below) or an original, first, and joint inventor (if plural inventors are named below or in an attached Declaration) of the subject matter which is claimed and for which a patent is sought on the invention entitled

## NON-STEROIDAL FARNESOID X RECEPTOR MODULATORS

Attorney Docket No. SALK 3130-1J (088802-9705)

the specification of which (check one)

is attached hereto.

was filed on <u>05/13/2005</u> as United States Application Number <u>10/535,041</u> based on PCT International Application Number <u>PCT/US2003/036123</u> filed on <u>11/14/2003</u> and was amended on <u>5/13/2005</u> (if applicable).

THAT I do not know and do not believe that the same invention was ever known or used by others in the United States of America, or was patented or described in any printed publication in any country, before I (we) invented it;

THAT I do not know and do not believe that the same invention was patented or described in any printed publication in any country, or in public use or on sale in the United States of America, for more than one year prior to the filing date of this United States application;

THAT I do not know and do not believe that the same invention was first patented or made the subject of an inventor's certificate that issued in any country foreign to the United States of America before the filing date of this United States application if the foreign application was filed by me (us), or by my (our) legal representatives or assigns, more than twelve months (six months for design patents) prior to the filing date of this United States application;

THAT I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment specifically referred to above;

THAT I believe that the above-identified specification contains a written description of the invention, and of the manner and process of making and using it, in such full, clear,

023.272782.1

concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention, and sets forth the best mode contemplated by me of carrying out the invention; and

THAT I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I HEREBY CLAIM foreign priority benefits under Title 35, United States Code §119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number	Country	Foreign Filing Date	Priority Claimed?	Certified Copy Attached?
				Attachen

I HEREBY CLAIM the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below.

U.S. Provisional Application Number	Filing Date
60/426664	11/15/2002

I HEREBY CLAIM the benefit under Title 35, United States Code, §120 of any United States application(s), or § 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application Number	PCT Parent Application Number	Parent Filing Date	Parent Patent Number
10/658115		9/8/2003	- work Trumber

023.272782.1

Page 2 of 4

I HEREBY APPOINT the registered attorneys and agents at Customer Number

#### 30542

to have full power to prosecute this application and any continuations, divisions, reissues, and reexaminations thereof, to receive the patent, and to transact all business in the United States Patent and Trademark Office connected therewith.

I request that all correspondence be directed to:

Stephen E. Reiter
FOLEY & LARDNER LLP
Customer Number: 30542

Telephone: Facsimile:

(858) 847-6711 (858) 792-6773

I UNDERSTAND AND AGREE THAT the foregoing attorneys and agents appointed by me to prosecute this application do not personally represent me or my legal interests, but instead represent the interests of the legal owner(s) of the invention described in this application.

I FURTHER DECLARE THAT all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Name of first inventor	Michael R. Downes
Residence	San Diego, California
Citizenship	Australia
Post Office Address	3440 Lebon Drive, Apt. 4210
Inventor's signature	San Diego, California 92122
Date	

OL F.Y. 858

Atty. Dkt. No. SALK 3130-1J (088802-9705)

Ronald M. Evans  La Jolla, California  United States of America  1471 Cottontail Lane  La Jolla, California 92037	
United States of America 1471 Cottontail Lane	
United States of America 1471 Cottontail Lane	
1471 Cottontail Lane	
La Jolla, California 92037	
Ronald M. Evans	
0/17/05	
Robert Hughes	
Creve Couer, Missouri	
Great Britain	
800 N. Lindberg, O403	
Creve Couer, Missouri 63167	
Kyriacos C Nicolaou	
La Jolla, California	
United States of America	
La Jolla, California 92037	
A-41 ID 1	
3337 Clairemont Drive, #4	
San Diego, California 92117	
	Robert Hughes Creve Couer, Missouri Great Britain 800 N. Lindberg, Q403 Creve Couer, Missouri 63167  Kyriacos C Nicolaou La Jolla, California United States of America 9625 Blackgold Road La Jolla, California 92037  Anthony J Roecker San Diego, California United States of America

# This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

#### **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:
☐ BLACK BORDERS
☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
☐ FADED TEXT OR DRAWING
☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
☐ SKEWED/SLANTED IMAGES
☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
☐ GRAY-SCALE DOCUMENTS
☐ LINES OR MARKS ON ORIGINAL DOCUMENT
REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
□ OTHER:

### IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.